

Drug Safety & Pharmacovigilance

DS CERTIFICATE APPLICATION PACKET

Application Deadlines:

Domestic - Fall Semester: June 1 & Spring Semester: November 1
International - Fall Semester: April 15 & Spring Semester: October 15

College of Pharmacy
The University of Georgia Gwinnett Campus
Lawrenceville, Georgia



UNIVERSITY OF
GEORGIA

College of Pharmacy

*International Biomedical
Regulatory Sciences*

DS Certificate Application Packet

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Begin this process at least 6 weeks prior to the listed deadlines.

Follow these instructions carefully.

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Application Deadlines

Domestic - Fall Semester: June 1 & Spring Semester: November 1

International - Fall Semester: April 15 & Spring Semester: October 15

IMPORTANT NOTES:

1. This application is for the DS Certificate Program courses only. Courses completed in the certificate program may be used at a later time to fulfill a portion of the coursework for the Master of Science Degree with an emphasis in Regulatory Sciences so long as the coursework is still valid (8 years). The MS has a separate application process, and additional admission criteria are required. Please review the Department's website for the most up-to-date information.
2. This application is a *supplemental* department application specific to the Drug Safety and Pharmacovigilance Graduate Education Program. The application deadlines are listed above.
3. You also will need to submit a University of Georgia *Graduate School* application and supply the necessary information to the Graduate School. Drug Safety Certificate Program Deadlines take precedence over the UGA Graduate School deadlines.
 - This is a separate application process. The web address for UGA's Graduate School is grad.uga.edu/.
 - The UGA Graduate School code for the Chemistry, Manufacturing, and Controls Certificate Program is **CERT_2DSP**.
4. It is your responsibility to ensure that your application is complete and submitted by the deadline. Incomplete applications will not be considered. Admissions decisions will be made only on complete files.

Deadlines: Applications for admission and all supporting documents must be received by:

 - Domestic - Fall Semester: June 1 & Spring Semester: November 1

- International - Fall Semester: April 15 & Spring Semester: October 15
 - All materials must be received by the Drug Safety Office by the deadline noted.
5. For the most up-to-date information, be sure to check the program website at <https://online.uga.edu/degrees-certificates/graduate-certificate-chemistry-manufacturing-controls>
 6. Using the UGA Graduate School tracking system, you can follow your application status. Please do not contact the Regulatory Sciences Department. We are unable to discuss or track an applicant's status.
 7. We are happy to address specific application and program questions with the applicant only. Spouses, partners, significant others, parents, employers, etc., must not contact our office on behalf of an applicant.

The DS Certificate Program consists of the following courses:

PHAR 6010E – Introduction to the Pharmaceutical, Biotechnology, and Device Industries (4 credit hours)

PHRM 7230E – Ethical Issues in Research (3 credit hours)

PHAR 7100E – Biostatistical Applications for the Pharmaceutical and Biotechnology Industries (3 credit hours)

PHAR 6140E – Overview of Drug Safety Throughout Medical Product Lifecycle (4 credit hours)

PHAR 6310E – Good Clinical Practice Regulations for Drugs, Biologic Products, and Medical Devices (3 credit hours)

= Total Credit hours: 17

Drug Safety & Pharmacovigilance GRADUATE EDUCATION PROGRAM Certificate Program

Application Procedures

Admission Guidelines for the Graduate Certificate Program

All applicants:

Send to the Regulatory Sciences Department -

1. Completed Personal Information Profile that is a part of this document.
2. Current résumé outlining the applicant's clinical trials or regulatory affairs experience
3. A one-page **Statement of Purpose**
4. *Optional (if applicable)*: Letter of Support from the employer that supports the applicant's participation in this program and outlines the perceived benefit of this coursework to your professional work
5. Two recommendation letters using either the UGA Graduate School online recommendation option or the [Departmental Recommendation Form](#) attached to this document.

Send to the UGA Graduate School –

6. Completed UGA Graduate School Application found at grad.uga.edu/. The Graduate School Application must be submitted directly to the Graduate School using the contact information on the website. In general, Graduate School Application includes:
 - a. Completing the general application for admission as a **NON-DEGREE** Seeking student.
 - b. The program code to use is **CERT_2DSP**.
 - c. A brief Statement of Purpose
 - d. An Application-processing fee
7. Submit two (2) official copies of transcripts from the institution that awarded the highest degree; these must be in a sealed envelope, mailed directly from the awarding institution to the UGA Graduate School.

Please follow the application preparation procedures when submitting your application materials. Note: In order to be considered for the appropriate semester, deadlines must be followed.

All applicants:

- Print clearly or type all forms.
- Fully complete all Drug Safety & Pharmacovigilance Graduate Education Program application forms.
- Be sure to sign and date all signature blocks.

Have I included everything in my Admissions Portfolio?

Check List

To the RA Department:

- Personal Information Profile
- Current Résumé/Curriculum Vitae
- Statement of Purpose
- Two Letters of Recommendation using either the [Departmental Recommendation Form](#) within this packet or the UGA Graduate School online recommendation option.
- Optional:* Letter of Support from Employer
- You must also complete a University of Georgia Graduate School application at grad.uga.edu/.
- The RS department is unable to comment on the status of your application. Follow your application status using the UGA Graduate School online tracking system.***

Check List

To the UGA Graduate School:

- UGA Graduate School Application - you must also apply to the UGA Graduate School using their online application process, grad.uga.edu/.
- Two official copies of academic transcripts
- International students must supply TOEFL Scores.
 - Remember, for international students, our program does not offer student visa sponsorships or student assistantships.

Mailing Instructions

The Drug Safety Department Application materials must be received on or before the deadline for the term of enrollment. All materials must be received by the Regulatory Sciences Office by the deadline noted, not “post-marked by.” **Department Deadline is: Fall Semester: June 1 (domestic) & April 15 (international)**

You may send your information via email to beverlyminor@uga.edu. You may also send your information through US mail. Be sure to send only the completed application to the address below. Use the entire mailing address.

**International Biomedical Regulatory Sciences
The University of Georgia Gwinnett Campus
College of Pharmacy
2530 Sever Road, Suite 100
Lawrenceville, Georgia 30043**

Other Important Notes:

1) Use caution if sending any information by email. The College of Pharmacy email servers are not secure to handle sensitive information.

2) When you identify your preferred email address below, understand that it is YOUR responsibility to check your email regularly in order to receive timely information from the department and the University. The University recognizes e-mail as an official means of communication. It is, therefore, important that you check your email regularly. Failure to respond to requests in a timely manner can jeopardize your application. Be sure to add the **uga.edu** domain to your email **safe list** to ensure that you receive all university and departmental correspondence.

3) Information requested by the UGA Graduate School Admissions should be sent to their attention, grad.uga.edu/ or by email at gradadm@uga.edu.

4) Remember to review the program's tuition structure and e-rate at (estimate only) bursar.uga.edu/.

5) The department does not offer financial sponsorships or assistantships. It is the applicant's or student's responsibility to familiarize him or herself with the tuition and to seek out financial aid if needed. UGA's Office of Financial Aid URL is osfa.uga.edu/.

6) The Certificate in Regulatory Sciences is a separate application and process.

7) The Master of Science Degree in Pharmacy (with an emphasis in Regulatory Sciences) is a separate application and process. It includes a separate application form and supplementary admission criteria.

Academic Honesty: When you enroll at the University of Georgia, you are affirming your commitment to uphold the principles outlined in the Academic Honesty Policy. This policy, established by the Student Government Association and approved by the University Council on May 1, 1997, declares: "I will be academically honest in all of my academic work and will not tolerate academic dishonesty of others." By signing the Admissions Application, all students acknowledge their agreement to adhere to this code. It is essential for every student to familiarize themselves with this policy as it governs all academic activities at the university. Ignorance of the policy is not a valid defense in cases of alleged academic dishonesty. The complete Academic Honesty Policy can be found at <https://honesty.uga.edu/Academic-Honesty-Policy/>.

Personal Information Profile

DRUG SAFETY AND PHARMACOVIGILANCE CERTIFICATE PROGRAM APPLICATION

**Departmental Application Deadline: Fall Semester:
June 1 (domestic) & April 15 (international)**

Optional: Please submit an application photo of yourself or send a digital image to beverlyminor@uga.edu. This image will be used for the secure class composite directory.

Adobe Acrobat may be used to fill out this form

Personal Data

Please print or type responses to all sections of the application carefully. Attach additional sheets if necessary.

Name: _____ Gender: M ____ F ____
(Last, First, Middle Initial)

Name you prefer to be called: _____

Date of Birth: _____ Place of Birth: _____
(mm/dd/yyyy)

Please state your residency status: U.S. citizen ____ Permanent Resident ____ F-1 Visa ____
GA resident ____ Other ____ (identify) _____

Optional: Please check one of the following:

White, Non-Hispanic ____ Black, Non-Hispanic ____ Hispanic ____
Asian/Pacific Islander ____ American Indian ____ Other ____

Home Address:

Street City State & Zip Code

Phone: (____) _____ Alt Phone: (____) _____

Email: _____ This is your preferred email address. It is YOUR responsibility to check your email regularly in order to receive timely information. The University recognizes e-mail as an official means of communication. It is, therefore, important that you check your email regularly.

Business Name Position/Title:

Work Address:

Street

City, State, & Zip Code

Phone: (____) _____

Fax: (____) _____

Work Email: (or secondary email address) _____

Work History

Attach additional sheets as necessary. List starting with your current (or most recent) position the jobs that you have held:

| Employer | Position | City | State | Employment Dates |
|----------|----------|------|-------|------------------|
| Employer | Position | City | State | Employment Dates |
| Employer | Position | City | State | Employment Dates |
| Employer | Position | City | State | Employment Dates |

College or University

Name in chronological order the institution(s) which you have attended for college credit. Give the name of each institution, the dates of your attendance, and the degree received.

| <u>Name of School or College</u> | <u>From</u> | <u>To</u> | <u>Degree</u> |
|----------------------------------|-------------|-----------|---------------|
| | | | |
| | | | |
| | | | |

If you are currently attending a college or university, list the degree you are pursuing and/or courses you are now taking.

Certifications / Licensures

Please list here and describe in detail on your résumé any certifications and/or licensures (like CQE, RAC).

State

Type

I certify that the responses on this application form and all accompanying materials are true to the best of my knowledge, and I am aware that any knowing falsification heron may result in denial of admission. Further, it is my understanding that I shall not be considered for admission until I have submitted all my credentials.

Signature: _____
Digital signatures are accepted.

Date: _____

Recommendation Form

For Application to the Drug Safety and Pharmacovigilance Program

Adobe Acrobat may be used to fill out this form.

You may use the Graduate School Recommendation form or this form. For questions, contact the Regulatory Sciences Program coordinator at (678) 985-6809 or by email at beverlyminor@uga.edu

To the Applicant:

Two recommendation request forms are required and must be mailed under separate cover. One recommendation form should come from your current employer or supervisor unless self-employed.

Applicant's Name: _____
(Please print or type)

Your recommendation can be mailed to:

International Biomedical Regulatory Sciences Programs
The University of Georgia, College of Pharmacy
Gwinnett Campus
2530 Sever Road, Suite 100
Lawrenceville, GA 30043
Email: beverlyminor@uga.edu

Federal law grants students access to educational records after enrollment. I voluntarily waive my right of access to the information contained in the recommendation and agree that it shall remain confidential.

Applicant's Signature: _____ Date: _____

To the Recommender:

Recommender's Name: _____
(Please print or type)

Business Name and Position/Title:

Address:

Street

City State & Zip Code

Phone: (____) _____ Fax: (____) _____

Email: _____

The Admissions Committee of the International Biomedical Regulatory Sciences Program of the College of Pharmacy at the University of Georgia appreciates your assistance in evaluating this applicant.

Please complete both pages of this form and return to the address above. Responses should involve specific knowledge relevant to the applicant's potential to study. The applicant has chosen you to make an honest, candid assessment of his/her abilities. Your recommendation will be considered in the admissions process.

Federal law grants students access to educational records after enrollment. Therefore, unless the statement above which waives access, is signed by the applicant, we cannot guarantee the confidentiality of your recommendation.

How well do you know the applicant?

Very Well _____ Moderately _____ Slightly _____

How long have you known the applicant? _____

My relationship to the applicant is/was in the following capacity:

_____ Current Employer/Supervisor

_____ Past Employer/Supervisor

_____ Professional Colleague

_____ Instructor/Teacher/Professor

_____ Friend/Acquaintance

Other (please specify): _____

How would you rate the applicant for each of the following characteristics? Please click on the box that best describes the applicant to insert the ✓ or X in the appropriate field.

| Characteristic | Outstanding | Good | Fair | Poor | No basis for assessment |
|------------------------------------------------------------------|--------------------|-------------|-------------|-------------|--------------------------------|
| Goal Orientation (motivation) | | | | | |
| Intellectual ability (keenness, capacity) | | | | | |
| Professionalism (promptness, perseverance, dependability) | | | | | |
| Dedication | | | | | |
| Organization Skills | | | | | |
| Initiative (independence, resourcefulness) | | | | | |
| Character (integrity, honesty, responsibility, ethics) | | | | | |
| Maturity (leadership, assertiveness) | | | | | |
| Personality (self-confidence, sense of humor) | | | | | |
| Ability to work with others | | | | | |
| Communication (oral) | | | | | |
| Communication (written) | | | | | |
| Interest in Profession | | | | | |

Please express your opinions based on your contact with the applicant. You may share any information which would be relevant to his/her character, capabilities, performance, readiness, and motivation to complete the Regulatory Sciences Graduate Program. Your time and effort in this endeavor is of value to the Admissions Committee in their consideration of the applicant.

Please print or type. Attach additional sheets or letter if necessary.

Recommendation concerning admission (please check one):

- I highly recommend this applicant.
- I recommend this applicant.
- I recommend this applicant, but with some reservations.
- I am not able to recommend this applicant.

Signature of recommender: _____ Date: _____
Digital signatures are accepted.

Your recommendation can be mailed to:
International Biomedical Regulatory Sciences Programs
The University of Georgia, College of Pharmacy
Gwinnett Campus
2530 Sever Road, Suite 100
Lawrenceville, GA 30043
Email beverlyminor@uga.edu

Connectivity Expectations

If you are admitted into one of the Regulatory Sciences Programs, you must ensure the following: These are requirements. The inability to operate basic listed hardware and software will jeopardize admission or progression in the program.

Internet Access

This online program requires a reliable connection to the Internet. You are responsible for setting up your own connection to the Internet. A broadband connection of 384 Kbps or higher is strongly recommended due to the rich media content in many of the online courses.

Operating System

We are an MS Windows Operating System Program. If you opt to use another operating system, like Apple OS, you will need to get support from UGA's EITS Office.

Email

Make sure that you have provided both the Department and the University with your preferred email address. It is YOUR responsibility to check your email regularly to receive timely information. The University recognizes e-mail as an official means of communication. It is, therefore, important that you check your email regularly.

Be sure to add the **uga.edu** domain to your email **safe list** to ensure that you receive all university and departmental correspondence.

Online Courses

If admitted, UGA will provide you with a UGA MyID account giving you access to e-mail, eLearning Commons, and other services. It is your responsibility to make sure your MyID account and password is active. All your course materials will appear in eLC. We will use eLC to make announcements pertaining to this course. It is your responsibility to check your eLC News and Content Modules on a regular basis to make sure you keep current with the course.

Software & Hardware required

1. Microsoft Office Suite
2. Adobe Acrobat Reader (latest version) – If you have the full version of Adobe Acrobat, you do NOT need Adobe Reader.
3. At least two internet browsers
4. **Computer Microphone:** If your computer does not have a microphone, please get one.

Distance Learning & Time Management

Here are some points for you to consider before enrolling in an online distance education course:

- Distance learning courses give you greater freedom to schedule your work, but they also require more self-discipline.
- Some people learn best by interacting with other students, but online courses do not afford as much opportunity for this type of interaction.
- Distance learning courses require you to work from written directions, without face-to-face explanations by the instructor.
- Online courses require at least as much time as attending classes and completing assignments for campus courses.
- Online courses use technology for teaching and communication. You will need to be comfortable with such computer techniques as up and downloading your assignments and using email to transmit and receive course materials.
- Text-based materials are the primary source of directions and information in many online learning courses. Online courses may still require occasional trips to campus for orientation, exams and seminars.

Time Management Considerations

The Regulatory Sciences Graduate Program will require that you:

Estimates only

- Conduct independent learning (roughly 2-4 hours of lecture time per week per course plus additional self-study time estimated at 4-12 hours/week).
- Complete work assignments over the Internet (roughly 2-4 hours per week per course)